

GUIDELINES FOR REACHING A JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES

INTRODUCTION

The importation of animals and animal products involves a degree of risk to the animal health status of an importing country. The estimation of that risk and the choice of the appropriate risk management option(s) are made more difficult by differences among the animal health and production systems in OIE member countries. It is now recognised that significantly different animal health and production systems can provide equivalent animal health protection for the purpose of international trade, with benefits to both the importing and exporting country.

These guidelines are to assist [This paper describes how] OIE member countries [may facilitate trade by determining] to determine whether sanitary measures arising from different animal health and production systems may provide [an equivalent] the same level of animal health protection. It discusses principles which might be utilised in the determination of equivalence, and outlines a step-wise process for trading partners to follow in facilitating a judgement of equivalence. [whether that be] These guidelines are applicable whether equivalence applies at the level of specific measures or on a systems-wide basis, and whether the agreement applies to specific areas of trade or commodities, or generally.

BACKGROUND

Before trade in animals or their products may occur, an importing country must be satisfied that its animal health status will be appropriately protected. In most cases, the risk management measures drawn up will rely in part on judgements made about the animal health and production system(s) in the exporting country and the effectiveness of sanitary procedures undertaken there. Systems operating in the exporting country may differ from those in the importing country and from those in other countries with which the importing country has traded. Differences may be with respect to infrastructure, policies and/or operating procedures, laboratory systems, approaches to the pests and diseases present, border security and internal movement controls.

International recognition of the legitimacy of different approaches to achieving the importing country's appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the World Trade Organization (WTO) *Agreement on Application of Sanitary and Phytosanitary Measures* (the SPS Agreement).

[The SPS Agreement includes key provisions relating to the principle of equivalence. Article 4 of the Agreement addresses the obligation to accept objective demonstrations of equivalence:

Members shall accept the sanitary and phytosanitary measures of other Members as equivalent, even if these measures differ from their own or those used by other Members trading in the same product, if the exporting member objectively demonstrates to the importing member that its measures achieve the importing member's appropriate level of sanitary or phytosanitary protection.

Member shall, upon request, enter into consultations with the aim of achieving bilateral or multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

The reference in Article 5.6 to the obligation to be least trade restrictive in setting measures encourages consideration of equivalence:

Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

In G/SPS/19 of 26 October 2001, the WTO SPS Committee addressed the concerns of developing country Members regarding their difficulty in having equivalence of their measures accepted by importing Members. The decisions in that document have been taken into account in this document.]

Appendix V (contd)

Benefits of applying [the concept of] equivalence may include:

- . minimising costs associated with international trade by tailoring animal health measures to local circumstances;
- . maximising animal health outcomes for a given level of resource input;
- . facilitating trade by achieving the required health protection through less trade restrictive sanitary measures; and
- . decreased reliance on relatively costly commodity testing and isolation procedures in bilateral or multilateral agreements.

The [OIE *International Animal Health Code* [(the Code)]] recognises equivalence by recommending alternative sanitary measures for many diseases. Equivalence may be gained, for example, by enhanced monitoring and surveillance, by the use of alternative test, treatment and isolation procedures, or by combinations of the above. To facilitate the judgement of equivalence, Member Countries are encouraged to base their sanitary measures on OIE standards, guidelines and recommendations to the extent possible.

It is essential to apply the discipline of risk assessment (the primary scientific component of risk analysis) to the extent practicable in establishing the basis for a judgement of equivalence.

[In this regard, Article 5.1 of the SPS Agreement states:

Members shall ensure that their SPS measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations.

SCOPE

This paper provides guidelines for judging the equivalence of sanitary measures associated with animal health and production systems, and adopts a risk-based approach. Issues other than animal health (for example product quality) may also be the subject of equivalence determinations but are not addressed in this paper, nor are they covered by the SPS Agreement.]

DEFINITIONS

[Most of the definitions below have been taken from internationally agreed documents.

Appropriate level of sanitary or phytosanitary protection (ALOP): The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. NOTE - Many Members otherwise refer to this concept as the 'acceptable level of risk']

For the purposes of these guidelines [this paper], the following definitions apply:

ALOP (acceptable risk): a Member Country's stated goals in protecting its animal population from hazards, as reflected in legislation and other official documents;

Equivalence of sanitary measures: agreement by an importing and exporting country that the sanitary measure(s) proposed by the exporting country as an alternative to those of the importing country, achieve(s) the same [an equivalent] level of protection.

Hazard: A biological, chemical or physical agent in, or a condition of, an animal or animal product with the potential to cause an adverse health effect. [Any pathogenic agent that could produce adverse consequences on the importation of a commodity]

Level of protection (LOP): the protection actually afforded through the application of sanitary measure(s), described in quantitative or qualitative terms. LOP is distinguished from ALOP in that ALOP reflects the country's goals in terms of risk management; the aim of an importing country would be to ensure that there is no significant difference between the two.

Risk: The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified time period, as a result of a hazard.

Risk analysis: The process composed of hazard identification, risk assessment, risk management and risk communication.

Appendix V (contd)

Risk assessment: The evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of an *importing country*.

Sanitary measure: Any measure applied to protect animal health or life within the territory of the Member Country from risks arising from the entry, establishment or spread of a hazard.

[Measures such as those described in each Chapter of the Code which are used for risk reduction and are appropriate for particular diseases. Sanitary measures may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

Scenario pathway: In the context of import risk analysis, a 'scenario pathway' represents the ordered sequence of steps that leads to a particular outcome or event, and will have an 'initiating event' and an 'end-point'. Once the initiating event (production or selection of the commodity) and end-point (typically a pest or disease outbreak) of a scenario have been defined, the steps along each pathway may be identified.]

PREREQUISITE CONSIDERATIONS IN A JUDGEMENT OF EQUIVALENCE

Application of risk assessment

Application of the discipline of risk assessment provides a structured basis for judging equivalence among different sanitary measures as it allows a close examination to be made of the effect of a measure(s) on a particular step(s) in the [scenario] importation pathway, and the relative effects of proposed alternative measure(s) on the same or related steps.

[Hazard]

A judgement of equivalence needs to assess the sanitary measure in terms of its effectiveness regarding the particular hazard or group of hazards against which the measure is designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the importing country.

Categorisation of sanitary measures

Proposals for equivalence may be in terms of a measure comprising a single component of a measure (eg an isolation procedure, a test or treatment requirement, a certification procedure) or multiple components (eg a production system for a commodity), or a combination of measures. Multiple components or combinations of measures may be applied consecutively or concurrently.

Sanitary measures are those described in each Chapter of the Code which are used for risk reduction and are appropriate for particular diseases. Sanitary measures may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

For the purposes of judging equivalence, sanitary measures can be broadly categorised as:

- . *infrastructure:* including the legislative base (eg animal health law) and administrative systems (eg organisation of national and regional animal health authorities, emergency response organisations);
- . *program design/implementation:* including documentation of systems, performance and decision criteria, laboratory capability, and provisions for certification, audit and enforcement;
- . *specific technical requirement:* use of secure facilities, [process] treatment (eg retorting of cans), specific test (eg ELISA) and procedures (eg pre-export inspection).

A sanitary measure(s) proposed for a judgement of equivalence may fall into one or more of these categories, which are not mutually exclusive.

Appendix V (contd)

In some cases a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether [an equivalent] the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an exporting country's animal health and production system. For example, a determination of equivalence for a specific sanitary measure at the program design/implementation level may require a prior examination of infrastructure while a determination of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programs.

PRINCIPLES FOR JUDGEMENT OF EQUIVALENCE

In conjunction with the above considerations, determination of the equivalence of sanitary measures should be based on application of the following principles:

- . an importing country has the right to set the level of protection it deems appropriate (its ALOP) in relation to animal life and health in its territory; this ALOP may be expressed in qualitative or quantitative terms;
- . the importing country should be able to describe the reason for each sanitary measure ie the level of protection intended to be achieved by application of the identified measure against a hazard;
- . an importing country should recognise that sanitary measures different from the ones it has proposed may be capable of providing an equivalent level of protection;
- . there are benefits in applying the concept of equivalence to animal health and production systems;
- . countries should, upon request, enter into consultations with the aim of facilitating a judgement of equivalence;
- . any sanitary measure or combination of sanitary measures can be proposed for determination of equivalence;
- . an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, minimise administrative burden, and facilitate resolution of claims;
- . the exporting country should be able to demonstrate objectively how the alternative sanitary measure(s) proposed as equivalent will provide the same [an equivalent] level of protection;
- . the exporting country should present a submission for equivalence in a form that facilitates judgement by the importing country;
- . the importing country should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and according to appropriate risk assessment principles;
- . the importing country should take into account any knowledge of and prior experience with the *veterinary administration* or other competent authority of the exporting country;
- . the exporting country should provide access to enable the procedures or systems which are the subject of the equivalence determination to be examined and evaluated upon request of the importing country;
the importing country should be the sole determinant of equivalence, but should provide to the exporting country a full explanation for its judgement;
- . to facilitate a judgement of equivalence, Member Countries should base their sanitary measures on relevant OIE standards and norms [should be taken into account];
- . to ensure that equivalence will be maintained, the importing and exporting country should keep each other informed of significant changes to infrastructure, health status or programs which may bear on the judgement of equivalence; and

an importing country should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of an equivalency determination.

SEQUENCE OF STEPS TO BE TAKEN IN JUDGEMENT OF EQUIVALENCE

There is no single sequence of steps which must be followed in all determinations of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. The interactive sequence of steps described below may be useful for all sanitary measures irrespective of their categorisation as *infrastructure*, *program design / implementation* or *specific technical requirement* components of an animal health and production system.

This sequence assumes that the importing country is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a risk analysis.

Recommended steps are:

- . the exporting country identifies the measure(s) for which it wishes to propose an alternative measure(s), and requests from the importing country a reason for its sanitary measure in terms of the level of protection intended to be achieved against a hazard(s);
- . the importing country explains the reason for the measure(s), in terms which would facilitate comparison with an alternative sanitary measure(s) and consistent with the principles set out in this document;
- . the exporting country demonstrates the case for equivalence of an alternative sanitary measure(s) in a form which facilitates judgement by an importing country;
- . the exporting country responds to any technical concerns raised by the importing country by providing relevant further information;
- . judgement of equivalence by the importing country takes into account as appropriate:
 - the impact of biological variability and uncertainty;
 - the expected effect of the alternative sanitary measure(s) on all relevant hazards;
 - OIE standards and norms;
 - application of solely qualitative frameworks where it is not possible or reasonable to conduct quantitative risk assessment;
- . the importing country notifies the exporting country of its determination and the underlying reasons within a reasonable period of time:
 - recognition of the equivalence of an exporting country's alternative sanitary measure(s);
 - request for further information; or
 - rejection of the case for equivalence of the alternative sanitary measure(s);
- . an attempt should be made to resolve any differences of opinion over judgement of a case, either interim or final, by using an agreed mechanism to reach consensus (eg the OIE dispute settlement mechanism), or by referral to an agreed expert;
- . depending on the category of measures involved, the importing and exporting countries may enter into a formal equivalence agreement giving effect to the judgement or a formal acknowledgment of the equivalence of a specific measure(s) may suffice.

An importing country recognising the equivalence of an exporting country's alternative sanitary measure(s) needs to ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or very similar measure(s). Consistent action does not mean however that

a specific measure(s) proposed by several exporting countries should always be judged as equivalent as a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures.